Community Blood Bank Center

a non-profit organization

August 31, 1999

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sirs:

I am writing regarding your Guidance for Industry issued August 1999, **Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products.** I must confess my surprise and discomfort not only at the contents of the guidance, but at the confused thinking that seems to be the foundation of the guidance. This guidance is inconsistent, vague and arbitrary. Because I hold the mission, ideals and people at the FDA in high regard, I believe this guidance is unworthy of the agency. The recommended actions not only fail to protect the public they are likely to cause harm in the form of blood shortages.

As you are aware, the Food and Drug Administration must hold product safety as its highest priority. Unfortunately the agency has not lived up to this mandate in regards to nvCJD. In the words of the current guidance, "The transmissibility of nvCJD by blood or blood products is unknown..." Despite this statement of fact, the guidance fails to recommend the withdrawal and destruction of plasma derivatives from donors with potential exposure to nvCJD. The rationale used in the guidance to explain this failure (dilution, route of administration and processing) is so flimsy as to be laughable. In short, although epidemiologic data is lacking for nvCJD, yet we are being asked to accept that the risk of nvCJD should be ignored because classic CJD seems not to be transmitted by derivatives. It is almost inconceivable that this recommendation could come in a guidance that states, "...transmissibility cannot confidently be predicted from studies of CJD."

The current guidance recommends indefinite deferral of donors who have had a six-month cumulative stay in the UK. The idea of an arbitrary six-month standard is unacceptable. There is no scientific basis for this limitation. If travel to the UK were a risk factor for nvCJD our mandate would be to defer all of these donors. Examination of the available evidence seems to indicate that the assertion that residents of the UK are vectors of disease is unfounded. In the absence of any indication that the UK is facing an unprecedented public health disaster due to nvCJD deferral for travel there cannot be supported.

This guidance recommends lookback to recipients of products from "implicated" donors. The legitimate goals of lookback are to inform recipients of products that were potentially infectious allowing treatment, prevention of secondary infections and to allow medically appropriate counseling. Evaluation of the issue reveals compelling reasons not to recommend lookback: it appears that there is no transmission by transfusion, there is

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no apparent risk of secondary transmission, and there is no treatment available. One can only speculate as to the devastation to the lives of blood recipients that lookback would cause. The ultimate irony in this case is that a blood donor might be given the message that they do not need to take any action, yet a recipient of their blood product needs "medically appropriate notification and counseling".

As the current guidance points out, there have been no transmissions of nvCJD through bovine insulin despite 20 years of experience. Despite this strong objective evidence that this product does not transmit nvCJD the current guidance recommends indefinite deferral of blood donors who have received injectable products made from cattle in BSE endemic areas. The confusion and ill will that the recommendations of this guidance will promote would be justifiable if the concerns regarding bovine insulin had some scientific basis. The guidance itself provides the scientific evidence that these products do not transmit nvCJD.

As I indicated above, I believe the evidence clearly indicates the appropriate course of action for the Food and Drug Administration:

- All blood products (including derivatives) from donors with nvCJD must be withdrawn and destroyed.

- Because travel to the UK does not place a donor at appreciable risk for nvCJD these donors should not be deferred nor products recalled.

- Because of the lack of risk and the absence of benefit, lookback in cases of CJD and nvCJD it cannot be recommended.

- Because bovine insulin has been shown not to transmit nvCJD this should not be a deferral criterion.

These recommendations represent rational conservative actions that are supported by objective evidence.

The FDA guidance, **Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood,** is a fatally flawed document. The guidance is onerous, inconsistent and most importantly, fails to meet the agency's safety mandate. Public policy decisions must be based on all available evidence. The vague nature of the nvCJD issue invites assumptions and speculation. An FDA guidance is not an appropriate forum for such creativity. The Food and Drug Administration has an obligation to protect the American public. Fueling an impending blood shortage by adding regulatory teeth to this poorly constructed guidance is at odds with this obligation.

Sincerely,

David Witthaus
Executive Director / CEO

DW:elc

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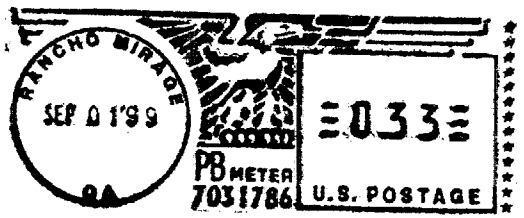

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